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FDA Approves First Test to Screen for West Nile Virus in Donors of Blood, Organs, Cells and Tissues

FDA today announced the approval of the first West Nile Virus (WNV) blood test to screen donors of blood, organs, cells and tissues. The Procleix WNV Assay, developed by Gen-Probe Inc., and marketed by Chiron Corporation, detects viral genetic material (ribonucleic acid or RNA). This new test will help protect patients who receive blood and other such products against West Nile infection. To date, there have been 30 documented cases of people who most likely acquired WNV from a blood transfusion, including nine who died.

"This approval is the result of a tremendous cooperative effort among FDA, other public health agencies, the test kit manufacturers and the blood industry," said Jesse Goodman, MD, MPH, director of FDA's Center for Biologics Evaluation and Research. "To develop an investigational test to screen blood, tissue and organ donors, and to get this test in blood banks throughout the country, and then licensed this quickly is a remarkable achievement for public health and patient safety."

West Nile Virus is typically transmitted to humans by mosquito bites. It was first detected in the United States in 1999, and has reoccurred each year for seven consecutive years, causing close to 20,000 human cases of disease and at least 762 deaths since 2002. It is estimated that between 1 and 2 million people have been infected with WNV.

In 2002, it was discovered that WNV could be transmitted in blood and an urgent effort to develop a blood test began. With support from FDA, the Centers for Disease Control and Prevention and the National Institutes of Health, manufacturers developed investigational WNV tests that were rapidly put in place both to evaluate their effectiveness and as an interim measure to protect the blood supply. Blood banks across the United States participated in these efforts, resulting in the detection and removal of approximately 1,600 infected donations, safeguarding the blood supply and providing the needed data for today's approval.

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